

**Notice of Allowability**

Application No.

09/898,425

Examiner

Blessing M. Fubara

Applicant(s)

VALDUCCI, ROBERTO

Art Unit

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to communication filed 07/11/05.
2. ☒ The allowed claim(s) is/are 35, 37 and 40-46 (Claims are renumbered).
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some\* c) ☐ None of the:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date 09/23/05.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

**THURMAN K. PAGE**  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600

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### **DETAILED ACTION**

Examiner acknowledges receipt of Appeal Brief filed 07/11/2005. Claims 35, 37 and 40-46 are pending.

### **EXAMINER'S AMENDMENT**

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with William J. Sapone on 09/23/05.

The application has been amended as follows:

In the claims,

Cancel claims 38 and 39.

Amend claim 35 as follows:

After "thereon" in line 11, insert ---, the active ingredient is selected from the group consisting of steroids, antibiotic, anti-inflammatories and combinations thereof, and mesalazine---

### ***Allowable Subject Matter***

2. The following is an examiner's statement of reasons for allowance:

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Hirakawa discloses pharmaceutical formulation that is controlled to release active agents at targeted site of the GI. In doing so, the control process in Hirakawa involves coating the core of the formulation with pH dependent enteric polymers such as the EUDRAGIT L and S or combination of the EUDRAGIT L and S polymers. The granules in Hirakawa can also have multiple layers of individual enteric polymers or mixed enteric polymers. See column 1, lines 8-14; column 4, lines 45-62; column 5, lines 46-57; column 6, lines 11-27 and Examples 3-5 for the active agent mesalazine or 5-Aminosalicylic acid. Khan et al. ("A pH-dependent colon targeted oral delivery system using methacrylic acid copolymers 1. Manipulation of drug release using EUDRAGIT L100-55 and EUDRAGIT S 100 combinations, J. of Controlled Release, 58, (1999) pp 215-222) discloses coated tablet formulation having coating comprising various combinations of two mathacrylic acid copolymers, EUDRAGIT L100-55 and EUDRAGIT S100 for pH-dependent release of active agents such as mesalazine in the GI. Hirakawa and Khan differ from the instant claims in that the claimed invention is directed to at least three sets of active ingredient portions, each portion set of active ingredient is coated with specific coating polymers or mixtures of specific coating polymers that is soluble at specified pH such that each ingredient portion set is released starting at the pH at which that polymer is soluble. None of these references have portions of active agents where each portion is specifically coated with specific polymer that begins to dissolve at a specified pH, the specific pH being a property of that polymer. For example, in the instant case, say, a group of particles begins to dissolve at pH 6.0; another group begins to dissolve at a pH of 6.5; and a third group begins to dissolve at a pH of 7.0. The prior art does not disclose this structure. Therefore, the pending claims are allowable.

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Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

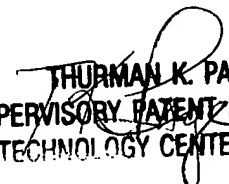
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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